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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,298	ALLEN, ANN DE WEES	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-9,11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-9 and 11-15 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed July 18, 2006 has been received and entered into the present application.

Claims 1-3, 5-9 and 11-15 remain pending and are under examination. Claims 1, 3, 5, 6, 8, 9, 11 and 12 are amended.

Applicant's arguments, filed July 18, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement (New Ground of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 3 is now drawn to the composition of claim 1 comprising particular dosage amounts *per serving* of the components detailed in the claim. Present claim 5 is now drawn to a

composition comprising an amino acid component and any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate and vitamin B5, wherein choline is present in said composition in an amount of 50 mg or less per serving. Present claim 9 is directed to the composition of claim 6 comprising particular dosage amounts *per serving* of the components detailed in the claim. Present claim 11 is now drawn to a method for stimulating muscle growth in a mammal comprising administering to a mammal a muscle growth stimulating amount of a composition comprising an amino acid component and any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate and vitamin B5, wherein choline is present in said composition in an amount of 50 mg or less per serving.

In particular, the specification as originally filed fails to provide written support for now claiming that (1) the dosage amounts of the components detailed in present claims 3, 5, 9 and 11 are amounts *per serving* and (2) that choline is present in an amount of 50 mg or less *per serving* of the composition described in present claim 1 or 6.

Applicant fails to provide reference to any portion of the specification that explicitly provides written support for now claiming that the dosage amounts of the components of present claims 3, 5, 9 and 11 are per serving or that the dosage amount of choline is 50 mg or less per serving of the composition described in present claim 1 or 6.

Applicant's sole disclosure of any amount *"per serving"* is the disclosure of arginine in an amount of 1.0-60.0 g per serving as recited in present claims 2 and 8. This, however, does not provide adequate written support to claim each of the recited dosage amounts of leucine, isoleucine, valine, chromium or choline, as g, mg or mcg amounts *per serving* of the composition as presently recited in claims 3, 5, 9 and 11 because neither the specification, nor the claims as originally filed, set forth the particularly claimed dosage amounts with sufficient specificity as amounts *per single serving* of the composition, but rather just as preferred dosage amounts. As a result, it is clear that the concept of the

particularly claimed dosage amounts as dosage amounts *per serving* of the composition was not present in the application as it was originally filed by Applicant.

Regarding the use of choline in an amount of 50 mg or less per serving of the composition described in present claims 1 or 6, a reasonable search of the specification demonstrates that Applicant has disclosed at page 9 of the specification the use of choline in the amount of 10.0-700 mg, preferably 50.0 mg (see Table at page 9). However, the preferable dosage amount of 50 mg is disclosed only insofar as it refers to the specific formulation that is described at page 9 of the specification, not as the preferable dosage amount of the broad composition that is actually claimed in present claim 1 or 6. The issue at hand is not whether Applicant has disclosed the actual amount of 50 mg or less in the specification or claims as originally filed, but rather whether the specification or claims as originally filed provide sufficient written support to now claim the broad composition of present claims 1 or 6 that further contains choline in the amount of 50 mg or less per single serving of the composition. In light of what Applicant has disclosed in the specification and claims as originally filed, the disclosure of a preferable amount of choline in the amount of 50 mg or less as a component of a much narrower composition (see Table at page 9) than that currently claimed in present claim 1 does not provide sufficient written support to now claim that same preferable amount as a component of the broadly claimed composition of present claim 1.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of (1) the dosage amounts of the components detailed in present claims 3, 5, 9 and 11 are amounts *per serving* or (2) that choline is present in an amount of 50 mg or less *per serving* of the composition described in present claim 1 or 6.

Accordingly, for these reasons, claims 3, 5, 9 and 11 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-9 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 1, for example, and also present claims 6 and 11, define compositions "wherein said composition has an essential amino acid component that consist of a muscle growth stimulating effective amount of L-arginine, L-leucine, L-isoleucine and L-valine and wherein said composition further comprises any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate and vitamin B5".

In particular, it is noted that the composition defined in present claims 1, 6 and 11 does not clearly delineate what components are intended to be included and what components are to be excluded from the composition because of the varying transitional language that is present in the claims. Applicant attempts to limit the amino acid component only to L-arginine, L-leucine, L-isoleucine, and L-valine, but allows for the overall composition to comprise any one or combination of ingredients selected from chromium, choline, sodium borate or vitamin B5, which also allows for the composition to be open to the inclusion of additional components. This may reasonably include, for example, other fructose, trans-ferulic acid or even other amino acids.

Though Applicant intends to exclude amino acids other than L-arginine, L-leucine, L-isoleucine from the composition, it is unclear how Applicant would attempt to actually achieve such an objective if

the composition is a homogeneous mixture and clearly allows for other components due to the fact that Applicant describes the overall composition with open language. Thus, for example, one could conceivably include additional amino acids other than the arginine, leucine, isoleucine and valine of the "amino acid component" as supplementary amino acids that are not considered part of the "amino acid component" *per se*. The claims, therefore, as written do not clearly convey the composition that it appears Applicant wishes to claim.

In addition, it is noted that present claims 3 and 9 do not narrow the subject matter of the independent claim from which they depend. In fact, it appears that present claims 3 and 9 actually broaden the composition of the independent claim because each of the claims recited "wherein said composition comprises per serving" and then goes on to describe the dosage ranges of each of the components. Regarding the amino acids, Applicant expressly recites the L-arginine, L-leucine, L-isoleucine and L-valine amino acid components, but it is noted that the use of the word "comprises" in the claim leaves the claim open to the inclusion of any one or more additional ingredients, which may, reasonably, include additional amino acids. Should Applicant desire to exclude additional amino acid components from the claimed composition, Applicant must actively recite such a limitation, provided, of course, that Applicant has sufficient written support to now claim such a limitation.

Therefore, it is noted that Applicant has not clearly, precise or deliberately set forth the metes and bounds of the claimed subject matter such that the skilled artisan would have been reasonably apprised of the scope of the subject matter for which Applicant is seeking protection. For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 1-3, 5-9 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant

regards as the invention.

In particular, it is noted that present claims 1, 6 and 12 are amended to now read upon "an effective amount of a composition having an essential amino acid component that consists of L-arginine, L-leucine, L-isoleucine and L-valine...". However, the use of the term "essential" in the newly amended claims is not commensurate in scope with what is presently disclosed in the specification.

Applicant's attention is directed to page 5 of the specification, which states, "Arginine is considered to be a semi-essential amino acid. It can be synthesized in animal tissue at a rate sufficient for maintenance in the adult but not rapidly enough to support growth in the young animal. It is thus an essential amino acid for growth but not for maintenance. It is difficult to obtain therapeutic amounts in chicken and turkey, thus the food supplement of arginine."

Though the phrase "essential amino acid" is one commonly used in the art to distinguish those amino acids that are "essential", i.e., those amino acids that cannot be synthesized *de novo* by a mammal and must be supplied in the diet, from those that are "non-essential", i.e., those that can be synthesized by a mammal, it appears from Applicant's disclosure that he does not intend to use the term "essential" in the manner commonly used in the art, but rather to denote whether the amino acid is necessary for growth and/or maintenance. Applicant states specifically in the specification that arginine is "semi-essential" (i.e., only essential for growth, but not essential for maintenance), not "essential", as presently claimed.

The claims as presently written encompass situations of both "growth" and "maintenance", absent factual evidence to the contrary, which in turn encompasses situations wherein arginine is either "essential" or "non-essential". However, the claims as written state that it is "essential" only, which is inconsistent with what is disclosed in the specification (see page 5 as stated *supra*), since during a period of maintenance, which is covered by the present claims, arginine would actually be "non-essential".

Additionally, it is noted that the only amino acid that is disclosed as being "essential" is arginine, not leucine, isoleucine or valine. Therefore, it is unclear how Applicant's addition of the limitation

"essential" to the "amino acid component" of the claims is intended to limit the leucine, isoleucine and/or valine component(s) of the composition.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and thus, do not reasonably apprise the skilled artisan of the scope of the presently claimed subject matter for which Applicant is seeking protection.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 15 is directed to "The method according to claim 14, wherein said immune system stimulator is vitamin C and is administered in an amount of 1-10 grams per day." There is insufficient antecedent basis for the limitation "said immune system stimulator" in claim 15, since any reference to such a condition in the claim from which it depends (i.e., claim 14 or claim 12) is noticeably absent. It is unclear how Applicant intends claim 15 to limit the presently claimed subject matter. As a result, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is properly rejected for rendering the scope of the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287; 1972), already of record, for the reasons of record set forth at pages 3-5 of the previous Office Action dated April 3, 2006, of which said reasons are herein incorporated by reference.

Present claims 6 and 7 are properly included in the present rejection because Winitz teaches an amino acid food composition comprising free amino acids (col.4, lines 30-31), such as L-arginine, L-leucine, L-valine or L-isoleucine, in combination with the vitamins d-calcium pantothenate and choline bitartrate (see Tables I and II, for example). Winitz further teaches an aqueous solution, emulsion or dry form for admixture with water or a gel form to be consumed as part of the diet, i.e., oral administration (col.17, lines 21-31 and also, for example, col.11, lines 7-32). Although Winitz does not expressly teach the muscle growth stimulating effects of the composition, such a characteristic is inherent to the composition because Winitz teaches the administration of a composition of identical components to that presently claimed to an identical host as that presently claimed. Therefore, any muscle growth stimulating effects that are attributed to the administration of the composition would necessarily result in the host, whether recognized by the patentee or not, because products of identical composition cannot exert mutually exclusive properties when they are administered in the same circumstances and/or environment, i.e., in this case, the host. Please reference MPEP §2112.

Applicant states that the essential amino acid component of the composition of the current invention is only arginine, leucine, isoleucine and valine and that Winitz teaches compositions with additional amino acids.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

In light of the manner in which the present claims are written, the fact that Applicant intends the specific "essential amino acid component" to be limited solely to the use of arginine, leucine, isoleucine and valine does not actually preclude the presence of additional amino acids in the composition because the overall composition as a whole is open to the inclusion of additional components resulting from the use of the transitional language of "has" and "further comprises" (see present claim 1). Though such additional amino acids may not be present in the "essential amino acid component" *per se*, the claim as presently written does not prohibit the inclusion of additional amino acids as a part of the claimed

composition as a whole. As stated *supra*, the composition as a whole is a homogeneous mixture and clearly allows for other components due to the fact that Applicant describes the overall composition with open language. The fact that a single portion of the composition may be limited to four amino acids does not limit the generic structure of the composition as a whole.

For these reasons, and those previously made of record at pages 3-5 of the previous Office Action dated April 3, 2006, rejection of claim 1 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287; 1972) in view of Durst (U.S. Patent No. 3,434,843; 1969) and Millman (U.S. Patent No. 4,871,550; 1989), each already of record, for the reasons of record set forth at pages 5-9 of the previous Office Action dated April 3, 2006, of which said reasons are herein incorporated by reference.

Regarding the limitations to dosage amounts "per serving" as recited in present claims 2, 3 and 5, the determination of the optimum dosage amounts of the active ingredients per single serving of the overall composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage amounts per single serving

that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with that which would have been determined by the skilled artisan. Additionally, in the absence of any evidence demonstrating the criticality of such concentrations, the optimization of the dosage amounts to maximize the efficacy of a composition when administered to an individual is considered a routine skill of the artisan. Please reference MPEP §2144.05.

Applicant relies on the remarks presented against the rejection under 35 U.S.C. 102(b) regarding the Winitz reference. Applicant additionally states that the secondary references to Durst and Millman also teach the presence of additional amino acids in the composition and do not address the problem of stimulating muscle growth in a palatable, efficient and metabolically favorable way.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

Regarding the assertion that the cited reference to Winitz, and also the cited secondary references to Durst and Millman, teach compositions with many additional amino acids, Applicant is directed to the Examiner's comments presented *supra* regarding Winitz, of which said comments apply equally to the teachings of Durst and Millman regarding the presence of additional amino acids in the composition.

Regarding Applicant's assertion that Durst or Millman do not address the problem of stimulating muscle growth in a palatable, efficient and metabolically favorable way, Applicant is reminded that present claims 1-3 and 5 are directed to a composition that is intended for use in the stimulation of muscle growth.

Applicant's intent to employ the presently claimed composition for stimulating muscle growth (as stated in the preamble of claim 1) is an intended use of the composition and does not patentably limit the presently claimed composition. A preamble limitation is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). A preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention and the preamble language extols benefits or features of the claimed invention that would necessarily be present in the prior art structure.

Please also see MPEP §2111.02[R-3], which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim)...During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim...If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)."

Regarding Applicant's assertion that Durst and Millman are not directed to the same use of stimulating muscle growth, such an argument is not persuasive because the fact that Applicant has recognized another advantage, i.e., stimulation of muscle growth, which would flow naturally from

following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., nutritional supplementation). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose their use in muscle growth stimulation is irrelevant because the combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention, regardless of the intended use of such components.

For these reasons, and those previously made of record at pages 5-9 of the previous Office Action dated April 3, 2006, rejection of claims 1-3 and 5 remains proper and is **maintained**.

Claims 6-9 and 11-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990), Dudrick et al. (U.S. Patent No. 5,026,721; 1991) and Boynton et al. (U.S. Patent No. 5,087,624; Issued 1992, Priority to 1987), each already of record, for the reasons of record set forth at pages 9-13 of the previous Office Action dated April 3, 2006, of which said reasons are herein incorporated by reference.

Regarding the limitations to dosage amounts "per serving" as recited in present claims 8, 9 and 11, the determination of the optimum dosage amounts of the active ingredients per single serving of the overall composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage amounts per single serving that would have actually been employed would have varied widely and, in the absence of evidence to the

contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with that which would have been determined by the skilled artisan. Additionally, in the absence of any evidence demonstrating the criticality of such concentrations, the optimization of the dosage amounts to maximize the efficacy of a composition when administered to an individual is considered a routine skill of the artisan. Please reference MPEP §2144.05.

Applicant states that the presently claimed composition with only four specific amino acids is highly effective in promoting muscle growth and excludes lysine from the composition. Applicant additionally states that, at the time of the invention, arginine and lysine were typically combined because lysine inhibited the growth of herpes 1 and 2 virus, which arginine "tends to promote" (see page 7 of Applicant's remarks). Applicant argues that the Dudrick et al. reference teaches the use of concomitant lysine, which is excluded from the present claims, and further submits that there is no disclosure in Rudman et al. suggesting the combined use of leucine, isoleucine and valine together.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

Regarding the exclusion of lysine from the presently claimed composition, the fact that Applicant intends the specific "essential amino acid component" to be limited solely to the use of arginine, leucine, isoleucine and valine does not actually preclude the presence of additional amino acids in the composition because the overall composition as a whole is open to the inclusion of additional components resulting from the use of the transitional language of "has" and "further comprises" (see present claim 1). Though such additional amino acids may not be present in the "essential amino acid component" *per se*, the claim as presently written does not prohibit the inclusion of additional amino acids as a part of the claimed composition as a whole. As stated *supra*, the composition as a whole is a homogeneous mixture and clearly allows for other components due to the fact that Applicant describes the overall composition with open language. The fact that a single portion of the composition may be limited to four amino acids does not limit the generic structure of the composition as a whole.

Furthermore, Applicant's arguments that the art would teach away from the exclusion of lysine from an arginine-containing composition in light of the herpes virus promoting effects of arginine, Applicant is first reminded that, as discussed *supra*, the claims do not definitively exclude lysine from the composition. However, even if the claims did exclude lysine, it is noted that Applicant's assertion that one of ordinary skill would have necessarily included lysine in combination with the arginine component is unsubstantiated by any evidence and is, therefore, not persuasive. Please reference MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)." It is also noted that although the presence of arginine alone may not be preferable to the skilled artisan, since, as Applicant has alleged on the record, it "tends to promote" herpes virus 1 and 2, such does not constitute a teaching away from a non-preferred embodiment, which, in the present case, would be the use of arginine alone in the absence of lysine. Applicant is reminded that, in accordance with the MPEP at §2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments."

Regarding the combined usage of leucine, isoleucine and valine, Applicant's assertion that there is no disclosure in Rudman et al. regarding the concomitant administration of leucine, isoleucine and valine is not persuasive. Rudman et al. teaches the administration of arginine for enhancing the release of growth hormone and increasing the muscle to fat ratio, i.e., increasing muscle mass, and Dudrick et al. teaches the administration of L-arginine, L-leucine, L-isoleucine and L-valine compositions for enhancing physical performance, particularly improving muscle growth and strength. Though Rudman et al. does not expressly teach the concomitant administration of leucine, isoleucine and valine, such does not change the fact that Dudrick et al. teaches the concomitant administration of these three amino acids for the same therapeutic purpose of enhancing physical strength and muscle growth for which Rudman et al. teaches

the administration of arginine. As a result, the combination of arginine, leucine, isoleucine and valine would have naturally commended itself, and would have been *prima facie* obvious, to one of ordinary skill in the art at the time of the invention because each was known in the art to be used for the same therapeutic objective and, therefore, would have been expected to exert additive, if not synergistic, strength enhancing effects when combined.

For these reasons, and those previously made of record at pages 9-13 of the previous Office Action dated April 3, 2006, rejection of claims 6-9 and 11-15 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-3, 5-9 and 11-15 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
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September 25, 2006

9/28/06
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SUPERVISORY PATENT EXAMINER